

SOP# HRP 04.03
Approval Date: 2/14/08

RESEARCH PERSONNEL – CONDITIONS FOR EMPLOYMENT OR WITHOUT COMPENSATION (WOC) APPOINTMENT

OBJECTIVES

- VAMHCS research personnel must either be a VA-paid employee or have a without-compensation (WOC) appointment to the VA.
- Research personnel must be qualified for and work within their Scope of Practice.

BACKGROUND

“Without Compensation “(WOC) appointments allow flexibility for staffing and collaboration on research studies while enabling the VA to ensure credentialing, qualifications, and trainings of collaborators and staff. WOC status also enables the VA to ensure compliance with VA policies such as intellectual property, data security, privacy of subjects, security of individually identifying information of subjects, etc.

DEFINITIONS

VAMHCS Research Personnel - any individual, regardless of who pays their salary, who is engaged in VAMHCS research and who meets at least one of the following criteria:

- The person works on research project(s) on-site in VAMHCS sites (see definition below);
- whose research work directly involves recruitment of or interaction with veterans within VAMHCS;
- The person has regular¹ verbal or physical contact with human participants in the VAMHCS system;

These individuals may include, but are not limited to principal investigators, sub-investigators, study coordinators, research assistants, data managers, lab personnel, pharmacy personnel, IRB staff, R&D Committee members, and Research Office staff. These individuals do not include secretarial support staff.

¹ At least monthly, on average

Credentialing – the formal, systematic process of verifying, screening and evaluating qualifications and other credentials that include education, licensure, relevant training and experience, and current competence.

Without Compensation (WOC) – status required for **VAMHCS research personnel** who are not VA-paid. Individuals who work off-site and who do not otherwise fit the definition of VAMHCS research personnel (above) do not need to obtain WOC appointments.

VAMHCS sites – locations where interactions with veterans, patients, samples and data can occur; sites are either VA property or VA-leased space.

RESPONSIBILITIES

Principal investigators are responsible for:

- ensuring that they and their staff have appropriate employment status at the VAMHCS;
- ensuring that the employee/WOC is qualified for the job and that the employee/WOC works within his/her scope of practice.

The VAMHCS Research Service is responsible for notifying WOC staff of annual renewals and changes in WOC documentation.

PROCEDURES:

1. See the definition of “VAMHCS Research Personnel” and “VAMHCS site” (above) to determine whether staff/collaborators fit the definition.
 - All research personnel who perform regular study-related activities at a VAMHCS site ***must*** be a VA-paid employee OR must obtain WOC status.
 - Research staff or collaborators whose study-related activities/interactions are ***entirely off-site***, do not need to be VA-paid employees or WOCs.
 - **“Off-site” staff or collaborators**
 - Do not need WOC status;
 - Must be adequately trained and licensed, as attested to by the PI;
 - Must comply with VA rules with regard to data use and privacy issues.
2. **WOC:**
 - 2.1. If the staff/collaborator fits the definition ***and*** is not VA-paid ***and*** performs regular study-related activities at a VAMHCS site, then the staff/collaborator must obtain WOC status.
 - 2.2. Report to the Research Service WOC coordinator to obtain required WOC paperwork.

3. Scope of Practice: See Research Service SOP: “Research Personnel - Scope of Practice” (HRP 04.04).
4. All VA-paid employees and WOC staff must complete VAMHCS mandatory trainings (see SOP 04.02) and must be able to produce proof of competency for all activities listed in their scope of practice document.

APPROVAL

This SOP entitled “Research Personnel Conditions for Employment or Without Compensation (WOC) Appointment” has been approved by the Medical Center Director, effective 2/14/08.